

TERMINATION OR SUSPENSION OF RESEARCH BY THE IRB

The convened IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB approval, that has been associated with serious or continuing noncompliance, or that has been associated with substantive harm to the rights and welfare of human subjects. Any suspension or termination of approval shall include a statement of the reason for the IRB action.

The IRB Manager, IRB Chair, or designee has the authority to request that the IRB suspend approval when the continuation of the research may adversely affect the rights and welfare of research subjects, or when the IRB needs additional information to ensure that the rights and welfare of subjects are protected and there is insufficient time to have the convened IRB review the situation.

The IRB reports the suspension or termination of approval promptly to the investigator, appropriate institutional officials, and the department or agency head, and includes a statement of the reasons for the IRB's actions. If the research is funded by an extramural agency, federal regulations dictate whether the funding agency must be informed that IRB approval has been suspended or terminated. Principal investigators (PIs) are responsible for informing the funding agency of any suspension or termination of funded research.

DEFINITIONS

A ***suspension*** of IRB approved research is a temporary interruption in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

A ***termination*** of IRB approval refers to a permanent halt in the enrollment of new subjects, activities involving previously enrolled subjects, or other research activities.

PROCEDURES

Suspension of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for suspending the research and any information needed from the PI and/or corrective actions or events that need to take place for the IRB to consider a withdrawal of the suspension.
2. If the IRB Chair or designee suspends IRB approval, the IRB Chair documents the reason for suspension and notifies the PI in writing or requests that IRB staff prepare the correspondence. IRB staff inform the IRB, and the IRB discusses the suspension at a convened meeting.
3. When a suspension involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of subjects to another investigator, arrangement of clinical care outside the research, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of subjects for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor.
4. IRB staff notify the PI in writing of the suspension. The correspondence may include, but is not limited to, the following:

- An explanation of the extent of the suspension in terms of enrollment, recruitment, interventions, interactions, and data analysis;
- The reasons for the suspension, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
- A request for a description of any procedures needed to protect the rights and welfare of current subjects if the suspension involves currently enrolled subjects;
- A description of whether follow-up of subjects for safety reasons is permitted or required.

5. The PI notifies enrolled subjects of any suspended research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.

6. The IRB determines which institutional officials to notify of the suspension and whether to report the suspension to an external agency.

Termination of IRB Approval

1. The convened IRB determines and documents in the minutes the reasons for terminating the research.

2. When a termination involves the withdrawal of current subjects from a research protocol, the IRB considers alternatives that protect subjects currently enrolled to ensure that harm is not incurred from such withdrawal. Such considerations may include possible transfer of subjects to another investigator, arrangement of clinical care outside the research, continuation of some research activities under the supervision of an independent monitor, permitting follow-up of subjects for safety reasons, or requiring reporting of adverse events or outcomes to the IRB and the sponsor.

3. IRB staff notify the PI of the termination. The notification may include, but is not limited to, the following:

- An explanation of the extent of the termination in terms of enrollment, recruitment, interventions, interactions, and data analysis;
- The reasons for the termination, an explanation of the reasons for the decision, and an offer to the investigator to respond to the convened IRB in writing;
- A request for a description of any procedures that need to be followed to protect the rights and welfare of current subjects if the termination involves currently enrolled subjects;
- A description of whether follow-up of subjects for safety reasons is permitted or required;
- An explanation that any request for the IRB to reconsider the termination must be made within 30 days from date of the notification.

4. The PI notifies enrolled subjects of any termination of a research protocol, and the PI considers the appropriate procedures for withdrawal of enrolled subjects, taking into account their rights and welfare.

5. The IRB determines which institutional official to notify of the termination and whether a report to an external agency is required.